

REMARKS/ARGUMENTS

Claims 1, 18 and 19 have been amended to recite "irradiating the protoplasts of (a)," to produce the chromosome fragments, support for which is set forth throughout the specification, including page 7, lines 13-16, Example 1, page 13, lines 17-18, page 14, lines 2-5, and page 15, lines 9-11.. Claim 2 has been amended to recite that the "irradiating" comprises irradiating with "gamma radiation," support for which is set forth on page 7, line 15 of the specification. Claim 12 has been amended to recite that the "recombination site is recognized by a site specific recombinase," support for which is set forth on page 11, lines 23-27 of the specification. Support for claim 43 is found in claim 10 and throughout the specification, and more specifically on page 6, lines 15-17. Support for claim 44 is set forth on page 11, lines 2-6. Claims 3, 10, 20-35 and 42 have been cancelled. No new matter is included in these amendments. Entry of these amendments is respectfully requested.

The Examiner rejected claim 10 under 35 U.S.C. § 112, ¶ 2. Claim 10 has been cancelled and rewritten in independent format in claim 43, which Applicants believe renders this rejection moot.

35 U.S.C. §112, ¶ 1

Claims 1-16 and 18-42 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement on three separate grounds, namely: 1) the specification does not enable fragmentation of chromosomes by any means other than gamma radiation; 2) a whole plant cannot survive radiation such that it can then be crossed and regenerated; and 3) the specification fails to teach one skilled in the art how to use non-recited constituents of chromosomes that may affect the functions of the nucleic acids. Claims 30-35 and 42 have been cancelled, thus

making the third ground of rejection moot. Applicants respectfully traverse the first and second grounds of rejection because *prima facie* non-enablement has not been established.

Claims 1, 18 and 19 recite "irradiating" the protoplasts of (a) to produce the chromosome fragments. These claims are enabled by the specification as well. In addition to the gamma radiation techniques taught in the specification (p. 7), the prior art cited by the Examiner teaches the use of other radiation techniques to produce chromosome fragments. For example, according to Hall et al., (1992, *Mol. Gen. Genet.*, 234, 234), "UV radiation results in substantial chromosome/chromatid fragmentation in these cells." Radiation techniques are further disclosed in other prior art of record. For example, Forsberg, et al. (*Theor. Appl. Genet.*, Vol. 96, 1178-1185, 1179-1182, 1998), teaches exposure of isolated donor protoplasts to either UV or X-irradiation to produce chromosome fragments and Gudowska-Nowak, et al., (*Radiother Oncol.* Vol. 73, 2:S123-126, Dec. 2004) teaches irradiating cells with C ions and X-rays.

In light of the various radiation techniques taught by the specification and prior art, Applicants submit that the claims are enabled, and respectfully request withdrawal of this ground of rejection.

Applicants submit that the second ground of rejection is unsupported by any evidence or reasoning, and thus amounts to a mere statement of doubt. This is insufficient to establish non-enablement. Aside from that, the very prior art cited by the Examiner illustrates regeneration of plants from fusions between irradiated and non-irradiated protoplasts. Specifically, Famelaer et al., (*Theor. Appl. Genet.*, Vol. 79, at 514), states, "Different plants were regenerated from each fusion product," indicating regeneration after irradiation. Likewise, Forsberg et al. (*Theor. Appl. Genet.*, at 1178-1179) (of record), describes a method by which radiated protoplasts were

fused and regenerated. In light of these teachings, persons skilled in the art would not have reason to doubt the statements contained in the patent specification regarding regeneration. For these reasons, Applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 103

The Examiner has rejected claims 1, 2, 5-16 and 18-42 as obvious over *Famelaer et al.*, (*Theor. Appl. Genet.*, Vol. 79, 513-520, 1990), in view of *Blume et al.*, (*Plant J.*, 12:731-746, 1997), and *Adam et al.*, (*Plant J.*, 11:1349-1358, 1997). The Examiner has determined that it would have been obvious to one skilled in the art to modify *Famelaer et al.* which teaches the production of parasexual hybrid plants through fusing gamma-irradiated protoplasts with non-treated protoplasts, by using protoplasts from transgenic plants as taught by *Blume et al.*, and YAC vectors as taught by *Adam et al.* (Office Action p. 6-7). Applicants respectfully traverse the rejection because *prima facie* obviousness has not been established.

The Examiner has rebutted Applicants' arguments, contending that Applicants have improperly addressed the cited publications "in isolation." It is well established that there must be some suggestion or motivation in the cited references themselves to combine the teachings of the references to establish a case of obviousness. As the Federal Circuit stated in *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1999) (reversing the Board of Patent Appeals' conclusion of obviousness), to prove obviousness the PTO must "particularly identify a suggestion, teaching, or motivation to combine" in the prior art. This standard was reiterated in *Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 50 U.S.P.Q.2d 1769 (Fed. Cir. 2001), when the Court affirmed the determination of non-obviousness where the prior art publications did not

demonstrate a motivation to combine. In particular, the court stated,

DeKalb cites to no specific language in either the Comai publication of the Barry patent demonstrating a motivation to combine. DeKalb merely refers to Barry's 'inherent teachings' without further explanation. Therefore, we agree with the district court's determination that claim 11 of the '471 patent is not obvious.

Rhone-Poulenc Agro, S.A., 50 U.S.P.Q.2d at 1784. Plainly, it is not legally improper and in fact, it is necessary to address the merits of each cited reference individually in the course of reaching a determination of non-obviousness.

None of the publications cited by the Examiner would have suggested or motivated one skilled in the art to combine their teachings. *Famelaer* teaches fusion of irradiated and non-irradiated protoplasts to create a parasexual hybrid plant containing some unpredictable number of chromosomes from a donor plant. (*Famelaer* at 513). *Famelaer's* teachings merely experiment with the possibility of transferring native (*i.e.*, non-exogenous) donor DNA via fusion of irradiated and non-irradiated protoplasts. (*Id.* at 516-518). *Famelaer* does not teach or suggest transformation of protoplasts with the exogenous nucleic acid before irradiation or how to select for artificial minichromosomes containing the exogenous nucleic acid, and that exhibit normal plant chromosomal activities, as claimed in the present application.

Blum and *Adam* simply disclose methods of plant transformation. More specifically, *Blume* teaches insertion of the GUS coding region into restriction enzyme sites in a plant transformation vector before introducing it into a plant. *Adam* teaches the use of YAC vectors that can be used to stably transform plant cells. There is no suggestion in either of

these publications to introduce the disclosed constructs into a protoplast, irradiate the protoplast to produce chromosome fragments, fuse the irradiated transformed protoplasts with non-irradiated protoplasts, and then select for minichromosomes containing the exogenous nucleic acid and which exhibit normal plant chromosomal activities.

The only way in which such a conclusion can be made is by the improper application of hindsight reconstruction of the claimed invention using the present specification as a template. As the Federal Circuit has stated,

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability - the essence of hindsight.

In *re Dembiczak*, 50 U.S.P.Q.2d at 999. As there is no motivation to combine the teachings of the cited references, Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with

Application No.: 10/030,793

Docket No.: ICON 3.3-002

this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 7, 2005

Respectfully submitted,

By Shawn P. Foley
Shawn P. Foley
Registration No.: 33,071
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

591233_1.DOC